

Can we prevent head lice?

Submission date 10/10/2012	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 19/10/2012	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 26/04/2016	Condition category Infections and Infestations	☐ Individual participant data

Plain English summary of protocol

Background and study aims

Head lice are still common in Britain despite the introduction of treatments that are not affected by resistance. This is mainly because not everyone treats the infestation at the same time. So many people would like to have a product that helps prevent infestations from arising. This study is to test a product designed to stop lice from establishing an infestation.

Who can participate?

This study is for the youngest person attending school from each household taking part who is at risk of head louse infestation. So the youngest will be 4 years old but there is no upper age limit otherwise.

What does the study involve?

If you fit the enrolment requirements you will first be treated on two occasions to make sure you don't have head lice, using Hedrin Once.

There are two study treatments. One is the active product (1% octanediol solution). This has the same active material as Hedrin Treat & Go but at a lower concentration, which has been shown to kill lice. The other product is a placebo (no active ingredient) that has the same appearance. Both products are used like a regular detangler and leave in conditioner spray. They need to be applied at least twice each week or, if you wash your hair more often, applied after each hair wash.

Everyone taking part will be randomly allocated to receive one of the treatments at the start of the study. They will use that product for 6 weeks. During that time one of our team will visit once each week to check for lice. If we find just one or two we will not do anything immediately because the active product takes a little while to take effect and the lice could have just arrived. However, at the next visit, if we find lice, we shall treat using Hedrin Once. At any time if we find newly hatched baby lice or more than five lice of any size we shall also treat using Hedrin Once. After the treatment you will continue with the same product until the end of the 6 week period. At the end of 6 weeks everyone will be treated again using Hedrin Once to make sure they have no lice again. After that they will change to the other treatment for 6 weeks, so everyone on the study will use both treatments. Because the bottles will be just labeled A or B neither the investigators nor the people using them will know which product is which.

Any other members of the family who catch lice during the course of the study will also be able to have a treatment to get rid of their lice while the study is running.

What are the possible benefits and risks of participating?

If the active product works as well as hope you should be protected from head louse infestation during the period you are using it. Also, at any time during the study, if you or family members catch lice they can be treated.

There are no known risks involved with this treatment, although some people may find their scalp is dryer than normal if they use too much product.

Where is the study run from?

The study is run by the Medical Entomology Centre in Cambridge.

When is study starting and how long is it expected to run for?

The study is starting in mid-October 2012 and will run until later February 2013, with a short break over the Christmas holiday period.

Who is funding the study?

The study is funded by Thornton & Ross Ltd, the makers of the Hedrin range of head louse treatment products.

Who is the main contact?

Ian Burgess, ian@insectresearch.com

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number

CTMK15

Study information

Scientific Title

A randomised, double-blind, cross-over, placebo controlled clinical trial to demonstrate the proof of concept for a product designed to protect against development of head louse infestation

Study objectives

To demonstrate the proof of concept that Octanediol 1% Solution is effective to limit the risk of development/growth of an infestation with head lice.

Ethics approval required

Old ethics approval format

Ethics approval(s)

NRES Committee North East - Northern & Yorkshire approved on 1st August 2012 , ref 12/NE/0253

Study design

Randomised double-blind cross-over placebo controlled clinical trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Head louse infestation

Interventions

All participants will be treated using 4% dimeticone gel on two occasions a week apart before starting on study treatments to eliminate any current infestation.

1. 1% 1,2-Octanediol solution

2. Placebo

Both preparations are applied in the same manner as detangling leave in conditioner sprays. Treatment is applied a minimum of twice each week or following every hair wash.

Participants receive one blinded treatment (either active or placebo) following the initial elimination of infestation. They continue for 6 weeks using the same treatment. After the 6 week period they are again treated using 4% dimeticone gel to eliminate any infestation not identified by investigators. They then change to the other blinded treatment, i.e. those on placebo change to active and vice versa.

If at any time during the study an active infestation is identified a further course of treatment using 4% dimeticone gel is instituted.

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Comparison of effectiveness of Octanediol 1% Solution, applied at least twice each week, compared with placebo to prevent or limit establishment of head louse infestation as measured by the time to first infestation with head lice during either of the six week periods on treatment.

Key secondary outcome(s)

1. Whether an infestation occurred during the six week period
2. The number of infestations occurring during the period, the safety of the product

Completion date

28/02/2013

Eligibility**Key inclusion criteria**

1. Both males and females attending school with no upper age limit, although they must be the youngest qualifying member of the household
2. People who are confirmed to be at risk of infestation with head lice
3. People who give written informed consent, or if the participant is under 16 years of age whose parent/guardian gives written informed consent to participate in the study
4. People who will be available for home visits by study team members over the 14 weeks of the study

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

Key exclusion criteria

1. People with a known sensitivity to any of the ingredients in Octanediol 1% Solution, Hedrin Once liquid gel or the placebo leave in conditioner preparation
2. People with a secondary bacterial infection of the scalp (e.g. impetigo) or who have a long term scalp condition (e.g. psoriasis of the scalp)
3. Pregnant or nursing mothers
4. People who have participated in another clinical study within 1 month before entry to this study
5. People who have already participated in this clinical study

Date of first enrolment

22/10/2012

Date of final enrolment

28/02/2013

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Medical Entomology Centre

Cambridge

United Kingdom

CB25 9AU

Sponsor information

Organisation

Thornton & Ross Ltd (UK)

ROR

<https://ror.org/00frd0c49>

Funder(s)

Funder type

Industry

Funder Name

Thornton & Ross Ltd, Huddersfield (UK)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	30/05/2014		Yes	No